)E: 6750-01-P

FEDERAL TRADE COMMISSION

[File No. 152 3021 / Docket No. 9397]

Health Research Laboratories, LLC; Analysis of Proposed Consent Order to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis of Proposed Consent Order to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order – embodied in the consent agreement – that would settle these allegations.

DATES: Comments must be received on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Interested parties may file comments online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write "Health Research Laboratories, LLC; Docket No. 9397" on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Elizabeth Averill (202-326-2993), Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained at https://www.ftc.gov/news-events/commission-actions.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Write "Health Research Laboratories, LLC; Docket No. 9397" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Due to the COVID-19 pandemic and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write "Health Research Laboratories, LLC; Docket No. 9397" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580. If possible, submit your paper comment to the Commission by overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov*, you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social

Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the *https://www.regulations.gov* website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC Website at http://www.ftc.gov to read this document and the news release describing the proposed settlement. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before **[INSERT DATE 30 DAYS AFTER DATE**

OF PUBLICATION IN THE *FEDERAL REGISTER*]. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see https://www.ftc.gov/site-information/privacy-policy.

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order from Health Research Laboratories, LLC; Whole Body Supplements, LLC; and their Managing Member and officer, Kramer Duhon ("Respondents").

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

This matter involves the Respondents' advertising for Black Garlic Botanicals, BG18, The Ultimate Heart Formula, and Neupathic. The complaint alleges Respondents violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that: (1) Black Garlic Botanicals, BG18, and The Ultimate Heart Formula will prevent, reduce the risk of, cure, mitigate, or treat cardiovascular disease, atherosclerosis, and/or hypertension; and (2) Neupathic will cure, treat, or mitigate diabetic neuropathy. Respondents Kramer Duhon and Health Research Laboratories are also parties to a previous federal court order in *FTC and State of Maine v. Health Research Laboratories, LLC, et al.*, 2:17-cv-00467-JDL (D. Me. Jan. 16, 2018).

The proposed consent order includes injunctive relief that addresses these alleged violations and contains provisions designed to prevent Respondents from engaging in similar acts and practices in the future.

Part I would ban Respondents from advertising, marketing, promoting, or offering for sale any dietary supplements. Part II would ban Respondents from making any disease prevention, reduction of risk, cure, mitigation, or treatment claim when advertising, marketing, promoting, or offering for sale any product.

Part III prohibits Respondents from making any representation about the health benefits, safety, performance, or efficacy of any food or drug, unless the representation is non-misleading, and at the time such representation is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of this provision, "competent and reliable scientific evidence" means tests, analyses, research, or studies that: (1) have been conducted and evaluated in an objective manner by experts in the relevant condition or function to which the representation relates; (2) are generally accepted by such experts to yield accurate and reliable results; and (3) are randomized, double-blind, and placebo-controlled human clinical testing of the product or of an essentially equivalent product, when experts would generally require such human clinical testing to substantiate that the representation is true. In addition, this provision requires that when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts as relevant to an assessment of such testing must be available for inspection and production to the Commission.

Part IV prohibits Respondents from making misrepresentations: (1) that the performance or benefits of any food or drug are scientifically or clinically proven or otherwise established; or (2) about the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

Part V requires Respondents to preserve supporting data and documents relevant to assessing human clinical tests that they rely on to support claims within the scope of Part III of the proposed order. Part VI requires Respondents to send notices to consumers who

purchased Black Garlic Botanicals, BG18, The Ultimate Heart Formula, or Neupathic informing them about this matter and the Commission's order. Part VII prohibits Respondents and their officers, agents, and employees from disclosing, using, or receiving any benefit from customer information that Respondents obtained in connection with sales of Black Garlic Botanicals, BG18, The Ultimate Heart Formula, or Neupathic. Part VIII requires Respondents to cancel any subscription plan with a negative option feature related to Black Garlic Botanicals, BG18, The Ultimate Heart Formula, or Neupathic.

Parts IX through XII of the proposed order relate to compliance reporting and monitoring. Part IX is an order acknowledgment and distribution provision requiring Respondents to acknowledge the order, to provide the order to current and future owners, managers, business partners, certain employees, and to obtain an acknowledgement from each such person that they received a copy of the order. Part X requires Respondents to submit a compliance report one year after the order is entered, and to promptly notify the Commission of corporate changes that may affect compliance obligations. Part XI requires Respondents to maintain, and upon request make available, certain compliance-related records. Part XII requires Respondents to provide additional information or compliance reports, as requested.

Part XIII states that the proposed order will remain in effect for 20 years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

By direction of the Commission.

April J. Tabor,

Secretary.

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